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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,090	06/21/2002	Stephen Arkinstall	220316USOPCT	7121
22850	7590	12/29/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,090	ARKINSTALL ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10/18/04.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,7-9,17-19 and 29-35, 38-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,7-9,17-19,29-35,38 and 39 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. This application is an RCE of SN 10/088,090.

Claims 2-6, 10-16, 20-28, 36-37, 40 have been canceled.

Claims 1, 7-9, 17-19, 29-35, 38-39 and newly added claims 41-45 are pending.

2. The rejection of claims 1, 7-8, 17-19, 29-35, 38-39 under 35 USC 112 first paragraph is now also applicable to claims 41-45 is maintained for reason of record.

Claims 1, 7-8, 17-19, 29-35, 38-39, 41-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Please note that the instant amendment limiting the scope of the generic concept to R3 and R4 are both hydrogen together with the subcombination of Markush elements as now recited in the "currently amended" claim 1 is NEW MATTER.

Removal of all NEW MATTER is required. In re Ressmussen 210 USPQ 325.

Per applicants' request in the preliminary response filed on Oct. 18, 2004, that the specification should be reviewed in accordance with the Sorenson 3 USPQ2d 1462 decision whether the disclosure *reasonably* convey to one skilled in the art that applicants are in possession of the instantly amended generic scope, the following observation was made:

On page 10 of the specification, an explicit description with respect to the generic support of the invention has been clearly provided that **at least one of R³ and/or R⁴ must be an amino acid** in combination with the generic concept of other Markush elements. Therefore, support for R³ and R⁴ are hydrogen to be combined with *the subcombination of Markush elements as now recited in the "currently amended" claim 1* was not found. NO GENERIC DESCRIPTION can be found for the instantly amended scope of R³ and R⁴ are both Hydrogen *together with the subcombination of Markush elements as now recited in the "currently amended" claim 1*.

The unsupportive nature of the currently amended generic concept of claim 1 was further noted that not only no description for the generic "concept" wherein both R3 and R4 are hydrogen to be combined with *the subcombination of Markush elements as now recited in the*

“currently amended” claim 1 was not found, the instantly amended claim 1 **does not encompass the explicitly disclosed species wherein both R3 and R4 are hydrogen.** Please note that all the compounds of claim 9 have an R6 being alkyl substituted with a “heteroaylamino” moiety (see CA 134:266198 structural delineation and nomenclature for the compounds). The instantly amended claim 1 is drawn to R6 being substituted C₁₋₆ aliphatic alkyl. Reading “substitution” of this alkyl moiety in light of the specification on pages 11-12 wherein the preferred embodiment was made for the R6 substitution (see paragraph bridging the two pages), ***none*** of the substituent is aryl or heteroaryl amino. It is noted that the substituents disclosed on page 11-12 paragraph bridging delineated semistructurally, are aryl-, heteroaryl-, NH₂aryl-, NH₂heteroaryl-, arylO-, heteroarylO- (please note that the bonding is at the last descriptive structure). To one having ordinary skill in the chemical art, no description or imaged description based on the above recited moieties in the specification can be read into a *heteroaylamino* which must be the requirement for claim 1 to encompass the compounds of claim 9. Therefore, a skilled person in the art given the specification as a whole would be provided that applicants are in possession of those compounds on page 12 lines 11-23, but no concept or any imagination can be found to support the instant amended claim 1 wherein claim 9 is improperly dependent upon since claim 1 does not read on claim 9 compounds.

3. Claim 9 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Please note that the base claim 1 as now amended, reading in light of the specification, does not contain the R6 moieties as found in claim 9, thus, claim 9 is broadening of the base claim.

4. Claims 1, 7-8, 17-19, 29-35, 38-39, 41-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention and was

not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Please note that as a correlated rejection as described supra in section 2, the claims lack description and enabling support. Not only the instantly amended claims do not contain compounds described in the specification, the method of using the compounds for such an array of enormous utility in treating all autoimmune diseases and/or neuronal system is incredible. Please note that autoimmune diseases including autoimmune haemolytic anaemia, autoimmune hepatitis etc. (see online print out from Medical dictionary) and a disease of the neuronal system encompassed from headache to schizophrenia to learning disability. No descriptive and enabling support can be found in the specification for such breadth.

Further, the claims of treating such disorder of the autoimmune and/or neuronal system constitutes “reach through claims”. Applicants are urged to consult the trilateral project B3b and In Print by Baker Botts for understanding of lacking 101 and 112 support with reach through claims. In addition, no nexus can be found in the record that a single active compound can be used in treating from epilepsy, to Alzheimer’s disease, to head drama, to spinal cord injury, and all autoimmune diseases for which no descriptive support can be found (see definition from Univ. oncology).

Further, the changing of modulating to “down regulate or inhibit” lacks antecedent basis in the specification. The argument that it is not necessary to have literal basis for the terms is erroneous. Please note that modulation encompassed both enhancement and inhibition. To change to down regulate *without* literal support is *new matter* since no descriptive support can be found that the *in vitro* inhibition is physiologically down regulation. Please note that physiologically, inhibition of “receptor” can be either up-regulation or down-regulation, no descriptive support can be found that such in vitro inhibition has any nexus to a physiological down-regulation as amended.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,646,149.

Vermeulin et al. '149 disclosed generically bispolyamines that are inhibitors of polyamine transport system. A structurally very close compound is disclosed on sheet 29, compound 1233 wherein the difference between the prior art compound and claim 1 is that a methylene is inserted between R3R4 carbon and the carbonyl moiety of the instant claim when R6 is substituted alkyl without limitation. The linker group being one or two carbon is taught generically at col. 15 lines 30-65. This generic teaching guided by the clear exemplification of the 1241 compound on sheet 29 rendered the instant one carbon linker obvious. The instant claim is merely the picking and choosing of a more limited combination of the generically disclosed alternatives by Vermeulin et al. '149. In absence of unexpected results, there is nothing unobvious in picking some among many of the prior art. In re Lemin 141 USPQ 814.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Celia Chang
Primary Examiner
Art Unit 1625

OACS/Chang
Dec. 22, 2004